RULE

Department of Health and Hospitals Board of Medical Examiners

Physician Practice; Marijuana for Therapeutic Use by Patients Suffering from a Qualifying Medical Condition (LAC 46:XLV.Chapter 77)

In accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et seq., and pursuant to the authority vested in the Louisiana State Board of Medical Examiners (board) by the Louisiana Medical Practice Act, R.S. 37:1261-1292, the board has adopted rules governing physicians who utilize therapeutic marijuana in the treatment of their patients who are suffering from a qualifying medical condition, LAC 46:XLV.Chapter 77. These rules are adopted in order to comply with the legislative mandate contained in Act 261 of the 2015 Session of the Louisiana Legislature, amending R.S. 40:1046, directing the board to promulgate such rules by January 1, 2016. The rules are set forth below.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions Subpart 3. Practice

Chapter 77. Marijuana for Therapeutic Use by Patients Suffering from a Qualifying Medical Condition

Subchapter A. General Provisions

§7701. Preamble, Warning, Suggested Consultation, and Rational for Terminology

- A. Preamble—State Law. Pursuant to Act 261, R.S. 40:1046, of the 2015 Session of the Louisiana Legislature, the Louisiana State Board of Medical Examiners was directed to:
- 1. promulgate rules and regulations authorizing physicians licensed to practice in this state to prescribe marijuana for therapeutic use by patients clinically diagnosed as suffering from glaucoma, symptoms resulting from the administration of chemotherapy cancer treatment, and spastic quadriplegia; and
- 2. submit to the Senate and House Committees on Health and Welfare on an annual basis not less than 60 days prior to the beginning of the Regular Session of the Legislature a report as to any additional diseases or conditions that should be added to the list of eligible diseases and conditions for prescription.
- B. Warning—Federal Law. Irrespective of Louisiana law, which as an agency of this state the board is obliged to adhere, marijuana is classified as a schedule I controlled substance under federal law and regulation and has not been approved by the United States Food and Drug Administration (USFDA) for the treatment of any medical condition. Prescribing marijuana is illegal under federal law and physicians who do so may be subject to criminal, civil and administrative consequences that include, among others, federal criminal prosecution, civil fines, forfeitures, penalties, revocation of controlled dangerous substance registration issued by the United States Drug Enforcement Administration, exclusion from Medicare and other federal payer programs, etc. Patients who possess marijuana, on the written request or recommendation of a physician or otherwise, may also be exposed to federal criminal prosecution, civil fines, forfeitures and penalties. Neither Louisiana nor the board's

rules preempt federal law, which may also impact the methods of payment to physicians for visits when therapeutic marijuana is requested or recommended and inhibit the deposit of proceeds from such visits into banks and other federally insured institutions.

- C. Consultation. For the foregoing reasons, physicians may wish to consult with their own legal counsel, as well as any health care facility, private or governmental payor with which the physician is affiliated, medical malpractice insurers and financial institutions before suggesting marijuana for the treatment of a qualifying medical condition in their patients.
- D. Rational for Terminology. Under Louisiana law, R.S. 40:961(32), the word *prescribe* means "[T]o issue a written request or order for a controlled dangerous substance by a person licensed under this Part for a legitimate medical purpose. The act of prescribing must be in good faith and in the usual course of the licensee's professional practice." Because some other states that have authorized physicians to issue a written request or recommendation or order for marijuana for qualifying medical conditions may be viewed as not directly transcending the federal prohibition against dispensing (and prescribing) marijuana and considering the definition of the word prescribe which was used in Act 261, these rules shall utilize the term written request or recommendation when describing a physician's direction to a licensed therapeutic marijuana pharmacy to provide marijuana for therapeutic use by patients who suffer from a qualifying medical condition. We do so with the caution that this attempt to minimize what may be viewed as a conflict between Act 261's direction to the board with controlling federal law by the use of this term in these rules, and in rules and laws of other states that have utilized the same or similar terms for this purpose, nevertheless remain subject to criminal, civil and administrative prosecution by federal authorities in the exercise of their discretionary authority to enforce federal law and regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2631 (December 2015).

§7703. Scope of Chapter

A. This Chapter is being adopted in order to comply with the obligations imposed upon the board by Act 261, R.S. 40:1046, of the 2015 Session of the Louisiana Legislature and govern a physician's written request or recommendation for the therapeutic use of marijuana for a patient suffering from a qualifying medical condition with whom the physician has established a bona-fide physician-patient relationship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015).

§7705. Definitions

A. As used in this Chapter, the following terms and phrases shall have the meanings specified.

Board—the Louisiana State Board of Medical Examiners, as established in R.S. 37:1261-1292.

Bona-Fide Physician-Patient Relationship—a relationship in which a physician:

- a. has conducted at least one in-person examination at a physical practice location in this state;
- b. maintains a medical record in accordance with professional standards; and

c. is responsible for the ongoing assessment, care and treatment of a patient's qualifying medical condition, or a symptom of the patient's qualifying medical condition.

Controlled Substance—any medication or other substance which is designated as a controlled substance and regulated as such under Louisiana or federal law or regulations.

Licensed Therapeutic Marijuana Pharmacy—a pharmacy located in this state that is licensed by and in good standing with the Louisiana Board of Pharmacy to provide therapeutic marijuana to a patient on the written request or recommendation of the patient's physician.

Marijuana—tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols in any form, except for inhalation, raw or crude marijuana, as permitted by the rules and regulations of the Louisiana Board of Pharmacy.

Medical Practice Act or *the Act*—R.S. 37:1261-92, as may from time-to-time be amended.

Patient—an individual who:

- a. is a resident of this state;
- b. has a current clinical diagnoses of a qualifying medical condition; and
- c. with whom the physician has a *bona-fide* physician-patient relationship.

Physical Practice Location in this State—a clinic or office physically located in this state where the physician spends the majority of his or her time practicing medicine.

Physician—an individual lawfully entitled to practice of medicine in this state, as evidenced by a current license duly issued by the board.

Prescription Monitoring Program or *PMP*—the prescription monitoring program established by R.S. 40:1001 et seq., as may from time-to-time be amended.

Qualifying Medical Condition—glaucoma, symptoms resulting from the administration of chemotherapy cancer treatment, spastic quadriplegia, and/or such other diseases or conditions that may subsequently be identified as a qualifying medical condition by amendment of R.S. 40:1046 or other state law.

Registrant—a physician who is registered with the board to issue a written request or recommendation for the use of marijuana for therapeutic purposes.

Written Request or Recommendation—written direction transmitted in a form and manner specified in §7721 of this Chapter, to a licensed therapeutic marijuana pharmacy. The issuance of a written request or recommendation must be in good faith and in the usual course of the physician's professional practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015).

Subchapter B. Prohibitions and Exceptions §7707. Prohibitions

- A. No physician shall:
- 1. issue a written request or recommendation for therapeutic marijuana unless he or she is registered with the board and complies with Louisiana law and the rules of this Chapter;
- 2. issue a written request or recommendation for therapeutic marijuana to more than 100 patients; provided, however, the board may grant an exception to this requirement pursua.nt to §7709.B of this Subchapter;

- 3. not delegate to any other healthcare professional or other person the authority to diagnose the patient as having a qualifying medical condition;
- 4. examine a patient at any location where marijuana is provided; or
- 5. have an ownership or investment interest established through debt, equity, or other means, whether held directly or indirectly by a physician or a member of a physician's immediate family, nor any contract or other arrangement to provide goods or services, in or with a licensed therapeutic marijuana pharmacy or a producer licensed by the Louisiana Department of Agriculture and Forestry to produce marijuana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015).

§7709. Exceptions

- A. The rules of this Chapter shall not apply to a physician's prescription of cannabinoid derived pharmaceuticals that are approved by the USFDA for administration to patients.
- B. Upon written application the board may, in its discretion, authorize a physician to exceed the patient limit set forth in §7707.A.2 of this Subchapter. The application shall contain a statement by the physician of the specific manner in which the physician proposes to deviate from such limit, together with a statement of the medical facts and circumstances deemed by the physician to justify such departure, and such other information and documentation as the board may request. The board's action on any such application shall be stated in writing and shall specify the manner and extent to which the physician shall be authorized to exceed the patient limit set forth in §7707.A.2 and the period of time during which such authorized exception shall be effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015).

Subchapter C. Registration

§7711. Registration, Physician Eligibility

- A. To be eligible for registration under this Chapter a physician shall, as of the date of the application:
- 1. hold a current, unrestricted license to practice medicine issued by the board;
- 2. hold current schedule I authority or such other authority as may be designated for therapeutic marijuana by the Louisiana Board of Pharmacy;
- 3. practice at a physical practice location in this state; and
- 4. complete an on-line educational activity available at no cost on the board's web page.
- B. A physician shall be deemed ineligible for registration who has:
- 1. has been convicted, whether upon verdict, judgment, or plea of guilty or nolo contendere, of a felony or any crime an element of which is the manufacture, production, possession, use, distribution, sale or exchange of any controlled substance or who has entered into a diversion program, a deferred prosecution or other agreement in lieu of the institution of criminal charges or prosecution for such crime;

- 2. has within the 10 years preceding application for registration, abused or excessively used any medication, alcohol, or other substance which can produce physiological or psychological dependence or tolerance or which acts as a central nervous system stimulant or depressant; or
- 3. is the subject of a pending formal investigation or administrative proceeding before the board.
- C. The board may deny registration to an otherwise eligible physician for any of the causes enumerated by R.S. 37:1285 or any other violation of the provisions of the Act.
- D. The burden of satisfying the board as to the qualifications and eligibility of the physician-applicant for registration shall be upon the applicant. An applicant shall not be deemed to possess such qualifications unless the applicant demonstrates and evidences such qualifications in the manner prescribed by and to the satisfaction of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015).

§7713. Application

- A. Application for registration shall be made in a format approved by the board and shall include:
- 1. the applicant's full name, contact information, and such other information and documentation as the board may require;
 - 2. criminal history record information; and
 - 3. an application fee of \$75.
- B. The board may refuse any application that is not complete and may require a more detailed or complete response to any request for information in the application.
- C. Applications and instructions may be obtained from the board's webpage, www.lsbme.la.gov, or by contacting the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, 1281, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015).

§7715. Registration Issuance, Expiration, Renewal

- A. If the qualifications, requirements, and procedures set forth in this Chapter are met to the satisfaction of the board, registration shall be issued to the applicant.
- B. Registration shall expire and become null, void, and to no effect the following year after issuance on the last day of the month in which the registrant was born.
- C. Registration shall be renewed annually on or before its date of expiration by submitting to the board a renewal application and a renewal fee of \$50.
- D. Registration which has expired as a result of nonrenewal may be reinstated upon the applicant's satisfaction of the qualifications, requirements and procedures prescribed for original application for registration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, 1281, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015).

Subchapter D. Marijuana for Therapeutic Purposes, Limitations, Access to Records

§7717. Use of Marijuana for Therapeutic Purposes, Limitations

A. Required Prior Conditions. Nothing in this Chapter requires that a physician issue a written request or

- recommendation for marijuana. However, if a physician determines it medically appropriate to do so to treat or alieve symptoms of a patient's qualifying medical condition the physician shall comply with the following rules.
- 1. Medical Diagnosis. A medical diagnosis of a qualifying medical condition shall be clinically established and clearly documented in the patient's medical record. The diagnosis shall be supported by an assessment of the patient, a review of the patient's medical history, prescription history, an assessment of current coexisting illnesses, diseases, or conditions, and an in-person physical examination.
- 2. Prescription Monitoring Program. The physician shall review the patient's information in the Prescription Monitoring Program database prior to issuing any written request or recommendation for marijuana.
- 3. Independent Medical Judgment. A physician's decision to utilize marijuana in the treatment of a patient must be based on the physician's independent medical judgment that the drug is likely to provide a therapeutic benefit in the treatment of the patient's qualifying medical condition and that such use would likely outweigh the health risks of other options that could be used for the patient.
- 4. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for the use of marijuana. The plan shall include documentation that other medically reasonable alternative treatments for the patient's qualifying medical condition have been considered or attempted without adequate or reasonable success.
- 5. Informed Consent. A physician shall explain the potential risks and benefits of the therapeutic use of marijuana and any alternative treatments to the patient. Among other items, informed consent should caution against driving, operating machinery or performing any task that requires the patient to be alert or react when under the influence of the drug and the need for secure storage to reduce the risk of exposure to children or diversion by others. A physician shall also advise patients that therapeutic marijuana has not been approved by the USFDA for the treatment of any medical condition, that possession may be viewed as illegal under federal law and subject to federal (and workplace) enforcement action. Discussion of the risks and benefits should be clearly noted in the patient's record. If the patient is a minor a custodial parent or legal guardian shall be fully informed of the risks and benefits and consent to such use.
- 6. Continued Use of Marijuana. The physician shall monitor the patient's progress closely, re-examine the patient at intervals not to exceed 90 days to assess the benefits of treatment, assure the therapeutic use of marijuana remains indicated, and evaluate the patient's progress toward treatment objectives. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility that marijuana use is not masking an acute or treatable progressive condition or that such use will lead to a worsening of the patient's condition. Indications of substance abuse or diversion should also be evaluated.
- 7. Medical Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of the medical diagnoses of a qualifying medical condition, PMP inquiries, consultations, treatment plans, informed consents, periodic assessments, and the results of all other attempts which the physician has employed alternative to marijuana. A physician shall also document the

date, type, quantity, dosage, route, and frequency of each written request or recommendation for marijuana which the physician has made for the patient. A copy of a written request or recommendation shall suffice for this purpose.

- B. Termination of Use. A physician shall refuse to initiate or re-initiate or shall terminate the use of marijuana with respect to a patient on any date that the physician determines, becomes aware, knows, or should know that:
- 1. the patient is not a qualifying candidate for the use of marijuana under the conditions and limitations prescribed by this Section;
- 2. the patient has failed to demonstrate clinical benefit from the use of marijuana; or
- 3. the patient has engaged in diversion, excessive use, misuse, or abuse of marijuana or has otherwise consumed or disposed of the drug other than in compliance with the directions and indications for use given by the physician.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015).

§7719. Board Access to Records

A. The records required by this Subchapter shall be available for examination, inspection and copying by the board or its designated employee or agent at any reasonable time, but without the necessity of prior notice by the board. The failure or refusal of a registrant to make such records available pursuant to this Section shall constitute a violation of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2634 (December 2015).

§7721. Form of Written Request or Recommendation

- A. Required Contents. A written request or recommendation for therapeutic marijuana shall include:
- 1. the physician's name, address, telephone number, e-mail address, registration number issued under this Chapter, and Louisiana schedule I or other license number for therapeutic marijuana issued by the Louisiana Board of Pharmacy;
 - 2. the name, address and date of birth of the patient;
- 3. the date, name and address of the licensed therapeutic marijuana pharmacy to whom the written request or recommendation is being transmitted;
- 4. the form, amount, dosage and instructions for use of therapeutic marijuana in an amount which is not greater than that necessary to constitute an adequate supply for a period of one month, including amounts for topical treatment; and
- 5. confirmation that the written request or recommendation for the rapeutic marijuana is being submitted for the physician's patient as defined by and in and conformity with the rules of this Chapter.
- B. Approved Form. Direction provided to a pharmacist substantially in the form of the written request or

recommendation form prescribed in the Appendix to these rules (§7729) shall be presumptively deemed to satisfy the requirements of this Section.

C. Manner of Transmission. A written request or recommendation for therapeutic marijuana shall be transmitted by the physician or physician's designee to a licensed therapeutic marijuana pharmacy in a manner that provides for medical/health information privacy and security and is in compliance with rules promulgated by the Louisiana Board of Pharmacy. The pharmacy shall be selected by the patient from a list of licensed therapeutic marijuana pharmacies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2634 (December 2015).

Subchapter E. Sanctions, Effective Date, Severability §7723. Sanctions Against Medical License or Registration

A. For noncompliance with any of the provisions of this Chapter the board may suspend, revoke, refusal to issue or impose probationary or other terms, conditions and restrictions on any license or permit to practice medicine in the state of Louisiana, or any registration issued under this Chapter, held or applied for by a physician culpable of such violation under R.S. 37:1285(A)(6), and R.S. 1285(A)(30), respectively.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2634 (December 2015).

§7725. Effective Date

A. The effective date of the rules of this Chapter shall be November 20, 2016, or such earlier date on which final rules have been published in the *Louisiana Register* by the Louisiana Board of Pharmacy and the Louisiana Department of Agriculture and Forestry, in accordance with R.S. 40:1046.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015).

§7727. Severability

A. If any rule, provision, or item of this Chapter or the application thereof is held invalid as in excess of or inconsistent with statutory or constitutional authority, such invalidity shall not affect other rules, provisions, items, or applications, and to this end the rules and provisions of this Chapter are hereby declared to be severable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015).

§7729. Appendix—Form of Written Request or Recommendation for Therapeutic Marijuana

—THIS IS NOT A PRESCRIPTION— PHYSICIAN WRITTEN REQUEST OR RECOMMENDATION FORM

Section A. Patient's Physician Information (Required)

1. Legal First Name	2. Middle Initial	3a. Legal Last Name	3b. Suffix (Jr., Sr., III, etc.)
4a. Full Professional Address (street, city	(in LA), zip code) 4b. e-mail address 4c	e.fax number	
5. City	6. State	7. Zip Code	8. Telephone Number
9a. LSBME Registration No. for Therapet No.	9	9b. Schedule I No. (Board o	of Pharmacy) for Therapeutic Marijuana
Section B. Patient Information (F	Required)		
10. Legal First Name	11. Middle Initial	12a. Legal Last Name	12b. Suffix (Jr., Sr., III, etc.)
13. Date of Birth	Birth 14. Full Address of Patient [street, city (in LA), zip code]		
Section C. Patient's Qualifying M Th — Glaucoma — Symptoms from chemother — Spastic quadriplegia	is patient has been diagnosed with the f (A minimum of one cond	following qualifying medical condi	ition:
Section D. Form, Amount, Dose,	and Instructions for Use of Th	erapeutic Marijuana (Red	quired)
Section E. Certification, Signatur			
	a qualifying medical condition and that strative rules promulgated by the Louisi	this written request or recommend	curate. I further attest that the above-named lation is submitted by and in conformity with iners, LAC 46:XLV.Chapter 77.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, and R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015).

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